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A study testing new HIV treatment options for children and adolescents in Africa

Submission date
10/07/2026

Recruitment status
Not yet recruiting

Registration date
29/07/2026

Overall study status
Ongoing

Last Edited
17/07/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This is an international research study aiming to identify the best HIV treatment options for children and adolescents living with HIV in Africa. HIV is treated with antiretroviral therapy (ART), which must be taken for life to keep the virus under control and maintain good health. Although adults living with HIV have several treatment options available, children and adolescents have fewer alternatives if their treatment causes side effects or stops working. This study will compare different HIV treatment combinations to find out which treatments work best, are safest, are easiest to take, and provide the greatest benefits for children and young people living with HIV.

Who can participate?
Children and adolescents may be able to participate if they:
1. Are aged at least 4 weeks and under 15 years
2. Weigh between 3 and 30 kg
3. Are starting HIV treatment for the first time or are already receiving HIV treatment but their HIV is not well controlled
4. Have at least two treatment options available within the study that their doctor considers suitable for them
Participants will be recruited from Uganda, Zimbabwe, and Mozambique

What does the study involve?
Participants will be randomly assigned to receive one of several HIV treatment options that are considered appropriate for them by their doctor.
During the study, researchers will monitor:
1. How well HIV is controlled using viral load blood tests
2. Side effects and safety of treatment
3. How well participants are able to take their medication
4. How easy and acceptable the treatment is to take
5. Mental health and quality of life
6. The costs and cost-effectiveness of different treatment options
Participants will attend study visits and have routine assessments, including blood tests. They will be followed for at least 48 weeks after joining the study.

What are the possible benefits and risks of participating?
Possible benefits:
1. Participants may receive HIV treatments that are effective and appropriate for their needs.
2. Participants will receive regular health monitoring throughout the study.
3. Information gained from the study may help improve HIV treatment options for children and adolescents in the future.
Possible risks:
1. All HIV medicines can cause side effects, although not everyone experiences them.
2. Blood tests and study procedures may cause temporary discomfort.
3. A participant's assigned treatment may not work as well for them as expected.
4. Participants may need additional tests or clinic visits as part of the study.
The study team will closely monitor participants for any side effects or health concerns throughout the trial.

Where is the study run from?
The study is being conducted in Uganda, Zimbabwe, and Mozambique. It is organised by an international collaboration of researchers from the United Kingdom, Uganda, Mozambique, Zimbabwe, Italy, and the Netherlands.

When is the study starting and how long is it expected to run for?
November 2026 to December 2029

Who is funding the study?
The European & Developing Countries Clinical Trials Partnership (EDCTP)

Who is the main contact?
The Trial Management Team at University College London’s Innovative Clinical Trials Unit, mrcctu.chapas5@ucl.ac.uk

Contact information

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Additional identifiers

Study information

Scientific Title
CHAPAS-5: an adaptive platform trial for evaluation of novel treatment regimens in children and adolescents with HIV in Africa

Acronym
CHAPAS-5

Study objectives
The primary objective of CHAPAS-5 is to identify and rank the most effective antiretroviral therapy (ART) regimens for children and adolescents living with HIV, both for those starting treatment for the first time and those requiring a treatment change after failure of dolutegravir (DTG)-based therapy. Effectiveness will be assessed by the proportion of participants who are alive and have achieved viral suppression (HIV viral load <400 copies/ml) at 48 weeks.

Secondary objectives include comparing two-drug versus three-drug DTG-based regimens, evaluating DTG-based versus darunavir/ritonavir (DRV/r)-based strategies after treatment failure, comparing abacavir/lamivudine with tenofovir alafenamide/emtricitabine backbones, and assessing safety, acceptability, quality of life, and cost-effectiveness of the different treatment approaches.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Pragmatic open-label adaptive platform trial using the PRACTical design

Purpose
Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
CHAPAS-5 uses a novel design called the Personalized Randomized Controlled Trial (PRACTical) design. This means that each participant will be randomly allocated to receive a treatment from a list that contains only the treatment options that are appropriate for them.

Treatment will be given daily for the duration of the trial. Drug doses would be weight band-based as per WHO recommendations. In nested pharmacokinetic substudies we will be evaluating an expanded use of adult formulations.

Each participant will be followed up for at least 48 weeks; the trial will end when the last participant to be randomized reaches week 48.

Arm 1: ART naïve and ART experienced participants: dolutegravir/abacavir/lamivudine (DTG/ABC /3TC)
Arm 2: ART naïve and ART experienced participants: dolutegravir/tenofovir alafenamide /emtricitabine (DTG/TAF/FTC) or bictegravir/tenofovir alafenamide/emtricitabine (BIC/TAF/FTC)
Arm 3: ART naïve participants: dolutegravir/lamivudine (DTG/3TC)
Arm 4: ART experienced participants: darunavir/ritonavir (DRV/r) + tenofovir alafenamide /emtricitabine (TAF/FTC)
Arm 5: ART experienced participants: darunavir/ritonavir (DRV/r) + abacavir/lamivudine (ABC /3TC)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Dolutegravir, abacavir, lamivudine, tenofovir, emtricitabine, darunavir, ritonavir, bictegravir

Primary outcome(s)
1. HIV viral suppression measured using plasma HIV viral load testing, defined as being alive and having an HIV viral load <400 copies/ml, at week 48 (a repeat viral load result will be used if the initial viral load is ≥400 copies/ml)

Key secondary outcome(s)
1. HIV viral suppression measured using plasma HIV viral load testing, defined as being alive and having an HIV viral load <1000 copies/ml at week 48 (a repeat viral load result will be used if the initial viral load is ≥1000 copies/ml)
2. Cross-sectional HIV viraemia measured using plasma HIV viral load testing, defined as the proportion of participants with HIV viral load ≥50 copies/ml, ≥400 copies/ml, and ≥1000 copies /ml at week 48 (using the viral load measurement closest to the scheduled week 48 visit)
3. Emergent HIV drug resistance measured using HIV drug resistance testing at week 48
4. Serious adverse events, severe adverse events, and antiretroviral treatment (ART)-modifying events measured using adverse event reporting, assessed from baseline to week 48
5. New or recurrent WHO stage 3 or 4 clinical events or death, measured using adverse event reporting and study records, assessed from baseline to week 48
6. Change in CD4 count and CD4 percentage measured using CD4 cell count and CD4 percentage testing at baseline and week 48
7. Change in weight and BMI-for-age measured using weight and height measurements to calculate BMI-for-age at baseline and week 48

Completion date
30/12/2029

Eligibility

Key inclusion criteria
1. Aged ≥4 weeks to <15 years* with confirmed HIV infection
2. Weight ≥3 kg and <30 kg*
3. Written informed consent obtained (and assent if applicable)
4. Willing to adhere to a minimum of 48 weeks' follow-up

*Upper limits of 15 years and 30 kg are for initial treatment options and may be amended when further treatment options are introduced (through a protocol amendment)

If antiretroviral therapy (ART)-naive:
1. Planning to start first-line ART
2. Virologically unsuppressed with viral load (VL) ≥400 copies/ml at screening

If ART-experienced:
1. ART-experienced and on DTG-based ART and have been on DTG-based ART for at least 6 months prior to screening
2. Virologically unsuppressed for at least 3 months, demonstrated by two consecutive VLs ≥400 copies/ml in the last year; the second VL must be at screening
3. Received adherence counselling as per standard practice prior to screening

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
4 Weeks

Upper age limit
15 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Alanine aminotransferase (ALT) ≥5 times the upper limit of normal (ULN), OR both ALT ≥3 x ULN and bilirubin ≥2 x ULN at screening**
2. Severe hepatic impairment or unstable liver disease (as defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminaemia, oesophageal or gastric varices, or persistent jaundice), known biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones)
3. Severe renal impairment, defined as creatinine clearance <30 mL/min/1.73 m², at screening**
4. Severe life-threatening illness (not expected to survive beyond two weeks) as determined by the investigator's clinical judgement
5. Eligible for less than two permitted treatment options based on tables 3 (ART-naive participants) and 4 (ART-experienced participants)
6. Concurrent participation in another clinical trial of an investigational medicinal product (IMP), medical device or other intervention

Date of first enrolment
30/11/2026

Date of final enrolment
30/06/2028

Locations

Countries of recruitment
Mozambique

Uganda

Zimbabwe

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

Funder Name
European and Developing Countries Clinical Trials Partnership

Alternative Name(s)
The European & Developing Countries Clinical Trials Partnership, The European & Developing Countries Clinical Trials Partnership (EDCTP), European and Developing Countries Clinical Trials, Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, EDCTP

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available